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14. ABSTRACT

The first year of the Prevention of Low Back Pain in the Military clinical trial has been a tremendous success as the research team was able to complete all Year 1 tasks in a timely fashion. The research team was also able to accelerate the funding schedule so that Year 2 tasks could be started, resulting in the creation of a study specific website (https://polm.ufl.edu) that is used for general information and data collection purposes, submission of a manuscript, and recruitment of 1286 Soldiers by May 31st, 2007.

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INTRODUCTION

Low back pain (LBP) is a musculoskeletal condition that accounts for significant pain and disability, and consumes substantial medical and occupational costs annually. Specific to the United States Armed Forces, LBP was the second most common reason to seek healthcare and affects over 150,000 active duty Soldiers annually (MSMR 2003). Soldiers in the U.S. Army with LBP have the highest risk of disability 5 years after their injury. Furthermore, a military review suggests that LBP was the most common condition bringing about a medical board, with lifetime direct compensation costs estimated to reach into the billions of dollars. Therefore, reduction of disability from LBP is a significant research priority for the military.

Reduction of disability from LBP has been divided into 2 separate phases – primary and secondary prevention. Primary prevention refers to interventions and strategies that are implemented before a low back injury occurs.[2] Primary prevention reduces LBP related disability by reducing the total number of people who eventually experience an episode of LBP. Secondary prevention refers to interventions and strategies that are implemented during the acute episode of low back injury, before chronic symptoms occur.[1] Secondary prevention reduces LBP related disability by reducing the number of people who eventually experience chronic disability from LBP. We are proposing an innovative approach to LBP prevention by combining primary and secondary prevention strategies that have the potential to limit the development of chronic LBP in Soldiers.

Objective/Hypothesis

The purpose of the Prevention of Low Back Pain in the Military (POLM) trial is to determine if a combined prevention program is more effective at limiting the development of chronic LBP when compared to the effects of individual evidence-based prevention programs, or a traditional exercise program.

Specific Aims

Specific Aim 1: We will determine if a combined prevention program consisting of core stabilization exercise program(CSEP) and psychosocial educational program (PSEP) prevents the development of chronic LBP. During advanced individual training (AIT), United States Army Soldiers who volunteer will be randomly assigned to receive 1 of 4 prevention programs. Soldiers will be followed monthly during the first 2 years following AIT to measure LBP occurrence and severity with a web-based data collection system managed at the University of Florida.

Specific Aim 2: We will determine if the CSEP results in favorable changes in specific core musculature associated with reducing LBP. The CSEP activates specific core musculature that is important in preventing LBP. We will use real-time ultrasound imaging to measure changes in core musculature that occur during AIT. We will also determine if the PSEP results in a favorable change in LBP beliefs. The PSEP educates individuals in an evidence-based, psychosocial approach to the management of LBP, which can potentially decrease the likelihood of experiencing chronic LBP. We will use a validated self-report questionnaire to measure Soldiers' LBP beliefs regarding outcome and management. We will measure LBP beliefs at the beginning and end of AIT (a 12-week period).

Relevance: The results of this study will have several immediate applications for Soldiers. The widespread incorporation of effective preventative strategies will certainly result in a substantial reduction of LBP in the military. Programs that effectively prevent the occurrence and severity of LBP would benefit the U.S. Armed Forces by improving the readiness of their Soldiers, reducing economic burden, and limiting disability among Soldiers. For example, an average

cost of $136.02 per LBP visit was calculated for 2004. A 40% reduction in the recurrence of LBP after completing the CSEP would generate a cost savings of $3,343,230 by the 4th fiscal year (approximately 1/5 of the total cost of LBP for one FY).

Low back pain prevention programs are necessary to reduce the impact of musculoskeletal injury in the United States Military. Low back injuries are a significant cause of disability in the United States Army. For example in the United States Military, LBP was the second most common reason to seek healthcare and affected over 150,000 active duty Soldiers. Soldiers in the United States Army with LBP have the highest risk of disability 5 years after injury and a review suggests that LBP was the most common condition bringing about a medical board, with lifetime direct compensation costs estimated to reach into the billions of dollars. Clearly, quality clinical research producing evidence related to LBP prevention is warranted for the United States Military.

Programs that effectively prevent the occurrence and severity of LBP would benefit the United States Military by improving the readiness of their Soldiers, reducing economic burden, and limiting disability among Soldiers.

BODY

As outlined in our SOW, Year 1 was primarily dedicated to completed tasks that allowed us to begin recruitment. These tasks are outlined below:

Task 1: Conduct start-up activities (Year 1)

- Obtain institutional human subjects approval (8 – 10 months)
  - BAMC
  - University of Florida
- Hire study personnel (2 months)
  - Texas site - 1 study coordinator, 1 research assistant, 1 data manager
  - Florida site – 1 data manager
- Initial investigator meeting (1 month)
  - Site training for study personnel and training instructors
  - Develop Manual of Standard Operations and Procedures
- Develop the Database and Data Management Procedures (3 – 4 months)

All of these start-up activities were completed in Year 1, with details outline below.

- Institutional Review
  - BAMC human subject approval granted February 2006 and has been maintained continuously since then.
  - University of Florida human subject approval granted June 2006 and has been maintained continuously since then
  - USAMRMC HSRRB deferred review to BAMC June 2006.
- Study Personnel
  - Texas site fully staffed with hiring of Donna Cunningham, Jessica Dugan, and Alison Wright
  - University of Florida site fully staffed with hiring of Yang Li
- Investigator Meeting
  - Investigator and study personnel have weekly conference call and share on-line calendar
  - Steven George visited Texas site in April to finalize training of study personnel and manual of standard operations and procedures
- Database and Data Management Procedures
  - Resulted in creation of web-site which serves dual function of providing information on the clinical trial and place to enter follow-up data for Soldiers participating in trial
  - Data management team has on-going management of database and web-site

Recruitment tasks scheduled for Year 2 of the SOW were initiated ahead of schedule in Year 1. These tasks are highlighted below.

Task 3: Data management and follow-up (Years 2)

- Collect onsite post-training measures (ongoing)
  - Self-report measures
    - Measures of mental and physical function
    - Negative affect
    - LBP
  - Muscle function measures (ongoing)
    - Multifidi
    - Lateral abdominal musculature
    - Transversus abdominus
    - Erector spinae
- Update and maintain web-based data management system (ongoing)
  - System checks and fixes
  - Error checks and fixes

Most importantly, we were able to successfully recruit and train Soldiers earlier than originally planned, and a detailed recruitment and training summary is provided below.

1. Total projected number of subjects
   a. We need 2700 Soldiers with complete 2-year follow-up information to accomplish the study aims.
   b. This requires recruiting between 3600 – 4800 Soldiers (variation in estimate accounts for differences in follow-up rates).
   c. Initial estimates from piloting were that ~200 Soldiers/Company would be recruited.

2. Recruitment statistics to date (May 31st, 2007)
   a. Recruitment started week of February 12th 2007
   b. A new Company starts every 2-3 weeks.
   c. 6 Companies recruited to date
   d. 2268 Soldiers introduced to study
   e. 1651 Soldiers eligible for study (72%)
   f. 1286 Soldiers consented to study participation (78% of eligible Soldiers)
      i. 15% excluded for age
      ii. 38% excluded for having prior history of low back pain
      iii. 3% excluded for current low back pain
      iv. 3% unable to participate in unit physical training
      v. 1% excluded for pregnant status
      vi. 2% excluded for hip/pelvic fracture
   g. An average of 39 Soldiers per Company have been removed from the study for many reasons (academic, administrative, and health reasons).

3. Recruitment achievements
   a. Successful emersion of 232nd in POLM Trial with full support of Command.
   b. Company satisfaction with efficient procedures that limits disruption to training schedule developed by the POLM staff.
   c. Successful and ongoing training of over 25 physical therapy students (collaboration of multiple Universities) assisting the study in-kind with recruitment, physical examinations, and data collection.
   d. Efficiency

i. Based on successful pilot testing, we have developed an efficient system for recruitment that allows us to recruit ~ 200 Soldiers in 90 minutes. This includes study overview, consent and HIPAA forms, and completion of intake forms.
ii. Using 8 staff members (2 supported by grant and 6 in-kind students) we are able to complete 4 physical examinations in a 90 minute period.
iii. Weekly meetings with Companies to foster a working relationship and discuss study-related matters as needed.
iv. Reliability study for ultrasound imaging is completed.

e. Finalized Procedures
i. Monitoring of exercise programs during morning unit physical training (PT) sessions allowing research staff ability to interact with Cadre and Soldiers (using 4-6 in-kind students daily).
ii. Ultrasound Imaging and Physical Examinations-Protocols completed, timing of examinations minimized to reduce effect on Soldier training schedule; consistent compliance and communication with Soldiers and Cadre. Peformed at the beginning and end of AIT (using 2 full-time staff and 6 in-kind students daily).
iii. Education Class- One time class with extensive information on the Science of Back Pain given to Soldiers with PowerPoint, followed by short quiz and handout of Back Book (using 2 full-time staff and 4 in-kind students).
iv. Outprocessing-Takes place at the end of AIT. Each Soldier completes the follow-up information via the website (using 2 full-time staff and 4 in-kind students).

Detailed summary of Year 2 tasks for the database team is provided below.

1. Database and analysis achievements
   a. Have established team in place including 2 personnel supported by grant (Samuel Wu and Yang Li)
   b. Bi-weekly meetings with data-base team
      v. Design and maintenance of web-site
      vi. Creation of research forms for data collection
         1. On-line versions
         2. Print versions
      vii. Creation and maintenance of database
      viii. Troubleshooting of web-site
   c. Successful creation of web-based data collection
      ix. Preview of website available at: https://polm.ufl.edu

KEY RESEARCH ACCOMPLISHMENTS

Recruitment Summary and Projections

- At the recruitment location, we currently have over 30 staff members (2 investigators from the grant, 3 hired study personnel, and 25 physical therapy students providing their services the in-kind) to perform recruitment and study assessments. The in-kind students are a key to the success of being able to recruit 200 Soldiers in one morning's unit PT session, perform 4 physical examinations each morning, and monitor unit PT. All of these events occur at the same time and hence require a larger staff than originally projected.

- At this point in the POLM trial, we are recruiting an average of 177 Soldiers per Company. Some class sizes have been lower than estimated and have included many Soldiers that are > 35 years of age. Therefore, although 78% of all eligible participants are volunteering to participate, our absolute values are lower than estimated in the original grant proposal. If this trend continues, it will take approximately 30 Companies to complete the study at the required sample size.

- We recruit a new Company every 3 weeks, which means a recruitment time frame of 106 weeks = 90 weeks (30 Companies x 3 weeks) + 16 weeks (time for last Company to complete their training). Additionally, we have 2 exodus time periods to consider (AIT students off for holidays) for an additional 6 weeks. So the total recruitment time frame to complete study recruitment is 106 weeks + 6 weeks= 112 weeks (which is ~25 months or 2 years).

- We started recruiting in Feb 07. We anticipate recruitment completion in Feb 09. **This estimate is beyond what we anticipated for the proposal and operates under the assumption we will recruit all Companies consecutively.**

Recruitment Barriers

- To date, average Company sizes have been smaller than that during the 2006 pilot phase.

- There will be a loss of 9 in-kind students who facilitate recruiting and study assessments while away fulfilling academic requirements. These 8 weeks sessions take place during fall '07, spring '08 and fall '08. Additionally, the remaining 16 students will have a decrease in availability due to fulfilling other academic requirements. The students work over 150 hours per week (combined) towards the study.

- From April 07 through the end of the study, we will be working with 4 Companies simultaneously and during the 24 weeks the students are out of town on clinical affiliations, we will not be able to perform all study-related procedures. **This will likely result in a missed recruitment of a Company during each of these time periods.**

Consequences for Recruitment Barriers

- These effects due to recruitment barriers will be detrimental to the scientific quality of this proposal. Trained study personnel will have to be let go and length of recruitment will be truncated, resulting in a smaller sample size.

Proposed Solutions to Recruitment Barriers

- Company size is effectively out of our control; however, we will continue to monitor and anticipate larger Companies later in the year.

- Additional funding would be required to satisfactorily address barriers related to extending recruitment period and need for additional personnel. Additional funding that would extend study personnel for 1 additional year (i.e. a Year 5) would allow us to complete recruitment at the proposed sample size and keep our study personnel intact (i.e. not lose time due to re-training new staff).

Database and Analysis Summary

- Database team has been receptive to unanticipated changes in data collection procedures, resulting in different data entry methods than expected.

- Database team has successfully created POLM trial website that can be used to disseminate information and collect data.

Database and Analysis Barriers

- We originally planned for all intake forms to be completed electronically. However, the lack of a sufficiently large computer lab with 100% internet access required that Soldiers complete intake information via traditional paper forms. This posed a significant increase in logistical and administrative workload, requiring that our study personnel (2 full time, 1 part time, plus 25 in-kind students) spend an unexpectedly large percentage of their time associated with recruitment activities. **The result is there are no remaining funds available to perform data entry.**

- **The extended recruitment time will result in an extension of the personnel involved with data analysis and management.**

Consequences for Database and Analysis Barriers

- These effects due to database and analysis barriers will adversely affect the scientific quality and dissemination of study results. Data will not be entered in a timely manner, potentially prolonging generation of data reports and analysis plans. Also, data analysis team may only be able to analyze follow-up rate from reduced time point (i.e. 1 year instead of 2 years).

Proposed Solutions to Database and Analysis Barriers

- Additional funding would be required to hire separate data-entry personnel, and support the data analysis and management team in Year 5 for primary analyses.

REPORTABLE OUTCOMES

- TOTAL SUBJECTS RECRUITED AS OF MAY 31ST, 2007 = 1286

- CREATION OF POLM TRIAL WEBSITE (https://polm.ufl.edu) FOR GENERAL INFORMATION AND DATA COLLECTION PURPOSES

- METHODS MANUSCRIPT IN REVIEW WITH *BMC Musculoskelet Disor*
    - George SZ, Childs JD, Teyhen DS, Wu SS, Wright AC, Dugan JL, Robinson ME Rationale, design, and protocol for the prevention of low back pain in the military (POLM) trial (NCT00373009) *BMC Musculoskelet Disord,* in review.

- IN-KIND COLLABORATIVE EFFORT AMONG PHYSICAL THERAPY STUDENTS FROM 5 DIFFERENT UNIVERSITIES (U.S. ARMY-BAYLOR University, University of Florida, University of Texas- Health Science Center San Antonio, East Tennessee State University, Texas State University)

CONCLUSION

The first year of the POLM trial has been a tremendous success as the research team was able to complete all Year 1 tasks in a timely fashion. The research team was also able to accelerate the funding schedule so that Year 2 tasks could be started, resulting in the recruitment of 1286 Soldiers by May 31st, 2007.

The research team will focus on Reportable Outcomes as one area of improvement for Year 2. Much of our resources were focused on completing tasks that allowed us to successfully recruit subjects, since that was of primary importance for the success of this study. We expect to have more Reportable Outcomes in Year 2, as we have recently developed a plan for submitting 3 manuscripts in Year 2. In addition, an abstract will be presented at the Force Health Protection Conference in Louisville, KY in August 2007.

Continued success of the POLM trial involves pro-actively addressing the barriers identified in the Key Research Accomplishments section. To the point, if recruitment continues at the current rate, the POLM trial would benefit from an extra year of funding to allow for no stoppage in recruitment. This will allow us to complete the study, with the originally proposed sample sizes, thus making a meaningful impact on the prevention of low back pain.

REFERENCES

1. Frank JW, Brooker AS, DeMaio SE et al. Disability resulting from occupational low back pain. Part II: What do we know about secondary prevention? A review of the scientific evidence on prevention after disability begins. Spine 1996;21:2918-29.

2. Frank JW, Kerr MS, Brooker AS et al. Disability resulting from occupational low back pain. Part I: What do we know about primary prevention? A review of the scientific evidence on prevention before disability begins. Spine 1996;21:2908-17.

APPENDICES

None